PHYSICIAN ASSISTANT COMMITTEE

INITIAL STATEMENT OF REASONS

Hearing Date: 1 May 2008

Subject Matter of Proposed Regulations:

Section(s) Affected: 1399.502, 1399.541, 1399.610, and 1399.612

Specific Purpose of each adoption, amendment, or repeal:

Current regulations require physician assistants to obtain patient specific authority from the supervising physician prior to writing drug orders for Schedule II through V controlled substances.

Assembly Bill 3 (Stats. 2007, Chapter 376: Bass) eliminated this requirement if a physician assistant completes a committee-approved controlled substance education course and if delegated by a supervising physician.

This proposal would also establish course content, require a written examination, course time frames, and define course providers. Additionally, the proposal would also establish responsibilities with regard to course structure, certificates of completion, record keeping, and availability of certificate of completion for inspection by the physician assistant's employer, prospective employer, or the committee.

Factual Basis/Rationale

Factual basis for determination that each proposed change is necessary:

- 1) Amend Section 1399.502.
- 1. 1399.502(a) has been amended to delete reference to the Division of Licensing as the division has been eliminated from the Medical Board of California.
- 2. 1399.502(g) has been amended to delete "division" and replace with "Board" which means the Medical Board of California.
- 3. 1399.502(h) has been added to include the definition of the approved controlled education course.

2) Amend Section 1399.541.

Section 1399.541(h) has been amended to include the requirement that a physician assistant may not administer, provide, or issue a drug order to a patient for Schedule II through V controlled substances without advance supervising physician approval unless the physician assistant has successfully completed an approved controlled substance education course and been authorized by the supervising physician to administer, transmit, or provide drug orders for Schedule II through V controlled substances without advanced approval. This authorization shall also be included in a delegation of services agreement between a physician assistant and supervising physician.

This regulatory change does not mandate that a physician assistant complete a controlled substance education course. The course is only required by physician assistants who wish to administer, provide, or issue drug orders for Schedule II through V controlled substances without advance approval from a supervising physician.

This change will ensure that the physician assistant regulations conform to the requirements established by Assembly Bill 3 and Business and Professions Code Section 3502.1(c)(2).

3) Adopt Section 1399.610 and 1399.612.

Assembly Bill 3 amended Business and Professions Code Section 3502.1(c)(2) to require the Physician Assistant Committee the establish standards, including pharmacological content, for the controlled substance education course.

The committee established a task force to discuss implementation of AB 3 and specifically to address the development of the controlled substance education course.

The task force met on 19 December 2007 and again via teleconference on 25 January 2008. Both meetings were publicly noticed. The task force included professional and public members of the Physician Assistant Committee. Additionally, other task force members and participants included representatives from the Medical Board of California, California Academy of Physician Assistants, a physician assistant training program educator, and an educator with a specialty in pharmacology.

A survey was sent to all California physician assistant training programs to solicit input with regard to the course duration. The survey results were also reviewed and considered by the members of the task force.

Task force members discussed and reviewed course specifics, including, course content, written examination requirements, course time frames, verification of course completion, record keeping requirements, and course providers. These later items regarding record retention will assist the committee in disciplinary proceedings and its investigators as applicable.

Two California Board of Registered Nursing fact sheets, which addressed controlled substance education requirements, were reviewed.

Members of the task force discussed the recommended number of hours required to complete the course to ensure that physician assistants who take the course are adequately trained.

The members then reviewed and edited draft regulatory language developed by Physician Assistant Committee legal counsel. This draft language was presented to the full committee at its 6 February 2008 public meeting. Members voted to set the matter for a public hearing.

<u>Underlying Data</u>

Technical, theoretical or empirical studies or reports relied upon (if any):

- Assembly Bill 3 (Stats. 2007, Chapter 376; Bass).
- Agenda of 19 December 2007 Assembly Bill 3 Task Force Meeting. (minutes not available for this meeting)
- Minutes of 25 January 2008 Task Force Meeting.
- California Board of Registered Nursing fact sheet, "Advanced Pharmacology Continuing Education Course for Furnishing."
- California Board of Registered Nursing fact sheet, "Nurse Practitioner Schedule II Controlled Substance Education Requirements prior to applying to the DEA for Schedule II Authority."

Business Impact

This regulation will not have a significant adverse economic impact on businesses because it only affects individuals who wish to take the controlled substance education course.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.

Set for below are the alternatives which were considered and the reasons each alternative was rejected:

- 1) Not amend or adopt regulations. This alternative was rejected because AB 3 requires that the committee develop standards and approve controlled substances education courses offered to physician assistants.
- 2) Amend and adopt regulations to establish specific standards for physician assistant controlled substance education courses.

The committee determined that the second alternative was the most feasible because it will comply with the requirements of Assembly Bill 3.

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